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10/067,148	02/01/2002	Marie-Cecile Van de Lavoir	271/123	4804

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EXAMINER

KAUSHAL, SUMESH

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/067,148

Applicant(s)

VAN DE LAVOIR ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21,26-30,41-48,51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,26-30,41-48,51 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) IDS 1,2,3. 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

*Applicant's response filed on 06/20/03 has been acknowledged.*

*Claims 1-20, 22-25, 31-40 and 49-50 are canceled.*

*Claims 21, 26-30, 41-48 are amended.*

*Claims 21, 26-30, 41-48 and 51-52 are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121 (<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>). The fax phone numbers for the organization where this application or proceeding is assigned is **703-872-9306**.*

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 26-30, 41-48 and 51-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Pain et al, Development 122:2339-2348, 1996 (*reference of record on PTO-1449*).

The instant claims are drawn to a chimeric chicken or method of making the same wherein the chimeric chicken comprised of progeny of embryonic stem cells.

Pain teaches in-vivo differentiation of chicken embryonic stem cells (CEC) obtained from long-term in-vitro culture. Cited art further teaches irradiated cultured

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CEC obtained from Barred Rock black strain CEC were injected into the subgerminal cavity of stage X White Leghorn recipient embryos, which resulted in the hatching of chimeric plumage phenotypes (see claims 21, 41, 43-44). The cited art further teaches that regardless number of passages more than 50% of the hatched recipient embryos were chimeras with nearly 33% of plumage from donor phenotype (page 2344 col.2 para.2; page 2346, fig-8). The cited art further teaches CEC expressing ECMA-7, SSEA-1 and EMA-1 could be cultured for at least 35 passages i.e more than 160 days in the presence of LIF, a cytokine (page 2343 col. 1-2, fig-4). Regarding claims 26-30 and 45-48 and 51-52, the cited art teaches that it is well known in the art that cells derived from early chicken blastoderm will contribute to both somatic and germ line when injected into recipient embryos to form chimeras (page 2339, col.2 para.2). The cited art further teaches that long-term cultured CEC were capable of differentiating several lineages, which could be characterized lineage marker specific antibodies (page 2344 col. 1 para. 3).

In addition, if the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In instant case the chimeric chicken (as claimed) is indistinguishable from the cited art of record, since one skill in the art would NOT be able to differentiate the chimeric chicken as claimed herein from the chimeric chicken disclosed in the prior art of record. The genome of the chicken embryonic stem cells would be same even after long-term culture of 160 days, while maintaining the expression of antigens characteristic of chicken ES cells (see page 2343 col.2). Thus the cited art clearly anticipate the invention as claimed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 26-30, 41-48 and 51-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 41 recite claim limitation “contribution of the genome of embryonic stem cells is detected in the chimeric chicken”.

Claims 26 and 45 recite claim limitation “contribution of the embryonic stem cells is detected in extra-embryonic tissue”

Claims 27 and 46 recite claim limitation “contribution of the embryonic stem cells is detected in somatic tissue of chicken”

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It is unclear what is the "contribution" of the genome of embryonic stem cells or embryonic stem cells in this context. For example it is unclear whether the contribution of genome of ES comprises the gene products (i.e. cytokines or differentiation factors etc) or genetic recombination or an undefined property of the ES genome. Similarly it is unclear whether the contribution of ES comprises differentiated ES cells of different lineages or cellular products (cytokines or differentiation factors etc) secreted by the ES cells or undefined property of the ES.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838 (**571-272-0769**). The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on 703-305-1998 (**571-272-0781**). The fax phone numbers for the organization where this application or proceeding is assigned is **703-872-9306**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*S. Kaushal*  
Patent examiner



JEFFREY FREDMAN  
PRIMARY EXAMINER